

additionally administering to said patient one or more compounds selected from the group consisting of D-lysine, polylysine having a molecular weight in the range 1-60 kD, pharmaceutically acceptable salts thereof and carboxyl derivatives thereof, to reduce kidney retention of said cytotoxic or imaging agent.--

REMARKS

Status of the Claims

By this amendment, claim 38 is added. Upon entry of this Amendment, claims 1-9, 11-21, 23-29 and 31-38 will be pending in the application.

Claim 38 is added to further define claim scope. Exemplary support for newly added claim 38 is found in the specification and examples of the present application as well as in the parent application (U.S. Application No. 08/407,899).

Claim Rejections - 35 U.S.C. § 103

Claims 1-9, 11-21, 23-29 and 31-37 are rejected by the Examiner under 35 U.S.C. § 103 as being unpatentable over Behr et al. (Cancer Research, 55:3825-3834, 1995) and further in view of Grey et al. (U.S. Patent No. 5,380,513) and Raines et al. (U.S. Patent No. 6,840,296).

The present application is a continuation-in-part application of U.S. Application No. 08/407,899 (hereafter "the '899 application"), filed March 21, 1995. In the Office Action dated January 28, 2002 (paper No. 20), the Examiner asserted that a method of reducing kidney retention of a protein conjugate that is not an antibody or an antibody fragment conjugate is not supported by the '899 application. The Examiner stated that the priority date of the claims of the present application is the filing date of the continuation-in-part application, November 30, 1998. Applicants respectfully disagree with the Examiner and assert that the present claims are entitled to the priority date of the '899 application. Behr et al. (Cancer Research, 55:3825-3834, 1995) was published on September 1, 1995 and the '899 application was filed on March 21, 1995, therefore Behr et al. (Cancer Research, 55:3825-3834, 1995) is not valid prior art against the present claims. Since Grey et al. and Raines et

al. do not teach or suggest the method of the present invention, Applicants respectfully request reconsideration and withdrawal of the rejection.

Applicants do not dispute that the instant application is a CIP and that expanded examples and description were added to the instant specification. However, the mere fact that a specification contains new matter does not mean that a given claim is not entitled to an earlier prior date. To the contrary, each claim must be examined individually to determine whether the parent '899 application contains support for the claims in question. In the instant application, the claims are supported. There are no claims pending that are directed to the specific embodiments constituting the new matter that was added in the CIP.

In particular, the generic phrase in new claim 38, "a cytotoxic agent or imaging isotope", is the exact language contained in the '899 application (page 3, lines 18-22 of the application; column 2, lines 14-17 of the issued patent). On page 2, lines 1-8 of the '899 application (column 1, lines 33-39 of the issued patent), a description of a potential mechanism for renal uptake of peptides and small proteins is provided. This passage evidences that the specification is directed broadly to a method for reducing renal uptake of peptide and small protein conjugates (whether antibody or non-antibody), and those methods are exemplified with antibody or antibody fragment conjugates. One of ordinary skill in the art, reading the specification as a whole, would readily understand that applicants possessed a generic scope extending to all such cytotoxic or imaging agents that are susceptible to renal uptake. Coupling the specification's explicit reference to "cytotoxic or imaging agents" with the explanation of the mechanism and the explicit reference to peptides and small proteins, there is at least implicit support in the '899 application for the presently claimed invention and no basis to deny these claims their rightful priority date.

Verbatim support has never been required. The courts have held that a broadening omission of an element is permitted where the specification as a whole suggests it is not necessary to the operation of the invention. Compare *In re Peters*, 723 F.2d 891, 221 USPQ 952 (Fed. Cir. 1983) (In a reissue application, a claim to a display device was broadened by removing the limitations directed to the specific tapered shape of the tips without violating

the written description requirement. The shape limitation was considered to be unnecessary since the specification, as filed, did not describe the tapered shape as essential or critical to the operation or patentability of the claim.). “[T]he specification *as a whole* must be considered in determining whether the scope of enablement provided by the specification is commensurate with the scope of the claims.” In re Johnson, 194 USPQ 187, 195 (CCPA 1977), citing In re Moore, 169 USPQ 236, 238-239 (CCPA 1971) (emphasis in original).

The ‘899 application does not indicate that it is critical or essential that the conjugate is an antibody or antibody fragment conjugate, and in describing the background, strongly implies that the solution to renal uptake discovered by applicants would be applicable to non-antibody targeting proteins/peptides, as well as antibody fragments. The mechanism described in the ‘899 application is reducing renal uptake by administering an effective amount of one or more compounds selected from the group consisting of D-lysine, poly-D-lysine, and poly-L-lysine, or a pharmaceutically acceptable salt or carboxyl derivative thereof. Therefore, the ‘899 application supports a method for reducing kidney uptake of a protein conjugate that is not an antibody or an antibody fragment.

The ‘899 application contains support for a method of reducing kidney retention of a protein conjugate that is not an antibody or an antibody fragment conjugate. A method for reducing kidney uptake of an antibody or an antibody fragment conjugate is an embodiment of the invention disclosed in the ‘899 application. An antibody is a *protein* that is structured and coded to react to a specific antigen. *See* Online Biology Dictionary definition of “antibody” (attached). Thus, antibodies are a species of the protein genus. On page 2, lines 1-8 of the ‘899 application, a description of a potential mechanism for renal uptake of peptides and small proteins is provided. This passage evidences that the specification is directed broadly to a method for reducing renal uptake of peptide and small protein conjugates, and those methods are exemplified with antibody or antibody fragment conjugates.

The court has held that “[d]escriptions of species amounting in the aggregate to the same thing [as a generic description]” provide adequate support under 35 U.S.C. § 112,

paragraph 1. In re Johnson, 194 USPQ 187, 196 (CCPA 1977), quoting In re Welstead, 174 USPQ 449 (CCPA 1972). The '899 application, including the examples, background and summary sections, when fairly considered as a whole, describes a method for reducing kidney uptake of antibody fragment conjugates as well as other non-antibody cytotoxic agents that are susceptible to the problem of renal uptake.

Accordingly, withdrawal of the rejection is respectfully requested.

CONCLUSION

As the above-presented amendments and remarks address and overcome all of the rejections presented by the examiner, withdrawal of the rejections and allowance of the claims are respectfully requested.

Applicants believes the application is in condition for allowance. However, in order to maintain pendency of the application, Applicants are filing a Notice of Appeal.

If the examiner has any questions concerning this application, he or she is requested to contact the undersigned.

Respectfully submitted,

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By Eve L. Frank

FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5109
Telephone: (202) 945-6142
Facsimile: (202) 672-5399

Eve L. Frank
Registration No. 46,785

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